

E-FILED on 3/26/10

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF CALIFORNIA  
SAN JOSE DIVISION

THE CENTRAL INSTITUTE FOR  
EXPERIMENTAL ANIMALS, a Japanese  
corporation,

Plaintiff,

v.

THE JACKSON LABORATORY, a Maine  
corporation,

Defendant.

No. C-08-05568 RMW

ORDER DENYING CIEA'S MOTION TO  
DISMISS JACKSON LABORATORY'S  
COUNTERCLAIM FOR PATENT  
INFRINGEMENT

[Re Docket No. 147]

The Central Institute for Experimental Animals ("CIEA") moves for dismissal of the Jackson Laboratory ("Jackson")'s counterclaim for patent infringement based on lack of standing. In the alternative, CIEA asks the court to certify the issue of Jackson's standing for interlocutory appeal. For the reasons set forth below, the court denies both the motion to dismiss and the request for certification for interlocutory appeal.

**I. BACKGROUND**

On December 12, 2008, CIEA filed a complaint against Jackson, alleging patent and trademark infringement and unfair competition. On February 11, 2009, Jackson filed an answer and brought counterclaims, including a counterclaim for infringement of U.S. Patent No. 5,912, 173

1 ("173 Patent). The '173 Patent is directed to the isolation, sequencing, and mutation of a particular  
2 mouse gene and is owned by the United States. According to Jackson, CIEA's NOG mouse<sup>1</sup>  
3 includes a genetic mutation covered by the '173 Patent. CIEA moved for dismissal of Jackson's  
4 patent infringement counterclaim based on lack of standing. On January 12, 2010, the court granted  
5 CIEA's motion and dismissed Jackson's patent infringement counterclaim with leave to amend. On  
6 January 27, 2010, Jackson filed a supplemental answer and counterclaims, again asserting  
7 infringement of the '173 Patent. CIEA now moves once more for dismissal of this patent  
8 infringement counterclaim for lack of standing.

## 9 II. ANALYSIS

### 10 A. Legal Standard for Standing Under 35 U.S.C. § 207

11 "The doctrine of standing . . . has both constitutional and prudential components." *Evident*  
12 *Corp. v. Church & Dwight Co., Inc.*, 399 F.3d 1310, 1313 (Fed. Cir. 2005). Under Article III of the  
13 Constitution, the constitutional component of standing requires the following elements: (1) the  
14 plaintiff has suffered an injury in fact; (2) there is a causal connection between the injury and the  
15 conduct complained of; and (3) it is likely that the injury will be redressed by a favorable decision.  
16 *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). In most patent infringement suits,  
17 plaintiffs that lack exclusionary rights fail to meet the injury in fact requirement because they suffer  
18 no legal injury when a party makes, uses, or sells the patented invention. *Morrow v. Microsoft*  
19 *Corp.*, 499 F.3d 1332, 1340-41 (Fed. Cir. 2007). In addition, the prudential component of standing  
20 in a patent infringement case generally requires that a patent owner be joined in any infringement  
21 suit brought by a licensee having fewer than all substantial rights in the patent. *Intellectual Property*  
22 *Development, Inc. v. TCI Cablevision of California, Inc.*, 248 F.3d 1333, 1347-48 (Fed. Cir. 2001).

23 However, 35 U.S.C. § 207 ("the Bayh-Dole Act") changed the standing requirements for  
24 government-owned patents. This statute authorizes federal agencies to:

25 *grant nonexclusive, exclusive, or partially exclusive licenses* under federally owned  
26 inventions, royalty-free or for royalties or other consideration, and on such terms and  
27 conditions, *including the grant to the licensee of the right of enforcement* pursuant to the  
provisions of chapter 29 of this title as determined appropriate in the public interest.

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28 <sup>1</sup> The "NOG mouse" is a severely immunodeficient mouse developed by CIEA's scientists.

1 35 U.S.C. § 207(a)(2) (emphasis added). The Federal Circuit's decision in *Nutrition 21* made clear  
2 that the prudential standing requirement of joining the patentee is no longer required for  
3 government-owned patents when the government grants the licensee the right to sue. *Nutrition 21*,  
4 930 F.2d at 867.

5 While contesting the previous motion to dismiss, the parties disputed whether the Bayh-Dole  
6 Act or *Nutrition 21* impacted the showing necessary to meet the constitutional standing requirement  
7 of injury in fact. After examining the purpose of 35 U.S.C. § 207 in light of the *Nutrition 21*  
8 decision, the court concluded that "injury in fact does not require exclusionary rights and can be  
9 satisfied by economic injury if: (1) the license is for a government-owned patent, (2) the government  
10 has granted the licensee the right of enforcement, and (3) the alleged infringing conduct is within the  
11 field of use for which the licensee has been granted patent rights, whether they be non-exclusive,  
12 exclusive, or partially exclusive." January 12, 2010 Order at 5.

13 **B. Jackson's Amended License Agreement**

14 The court granted CIEA's previous motion to dismiss Jackson's patent infringement  
15 counterclaim because it found that, although Jackson met the first two prongs of the test set forth  
16 above, CIEA's allegedly infringing NOG mouse was outside the scope of Jackson's licensed patent  
17 rights.

18 On January 22, 2010, the United States, through the National Institutes of Health, conveyed  
19 to Jackson a "non-exclusive license under the Patent rights with the right to sublicense the Central  
20 Institute for Experimental Animals (hereinafter CIEA) to make or have made, use of [sic] have used,  
21 sell of [sic] have sold, import of [sic] have imported and to offer for sale any CIEA owned or  
22 developed mice that have a mutated IL2rg gene." Def.'s Countercl. ¶ 15. With this amendment to  
23 its license agreement, Jackson re-asserted its counterclaim for infringement of the '173 Patent  
24 against CIEA.

25 The parties agree that under the newly amended agreement, Jackson has the non-exclusive  
26 right to make, use, sell, import, or offer for sale any CIEA owned or developed mice with a mutated  
27 IL2rg gene (in addition to its right to sublicense these rights). Thus, CIEA's NOG mouse now falls  
28 within the scope of Jackson's licensed patent rights.

1           **C.       CIEA's Claims**

2           Nonetheless, CIEA contends that the court should dismiss Jackson's counterclaim for failure  
3 to establish injury in fact. As discussed above, this court has held that, although injury in fact in  
4 patent infringement suits generally requires a showing of exclusionary rights, a non-exclusive  
5 licensee can satisfy the injury in fact requirement with economic injury if: (1) the license is for a  
6 government-owned patent, (2) the government has granted the licensee the right of enforcement, and  
7 (3) the alleged infringing conduct is within the field of use for which the licensee has been granted  
8 patent rights, whether they be non-exclusive, exclusive, or partially exclusive. January 12, 2010  
9 Order at 5.

10           It is undisputed that the first two parts of this three-part test have been met. CIEA argues  
11 that part three has not been satisfied. According to CIEA, Jackson's rights under the newly amended  
12 license are illusory and therefore do not provide a genuine nexus between Jackson's licensed rights  
13 and the infringing conduct. Alternatively, CIEA argues that the court's previous ruling is incorrect,  
14 i.e. even if the three-part test has been met, only exclusionary rights (and not economic injury) can  
15 satisfy the injury in fact requirement. The court addresses each argument in turn.

16                   **1.       Illusory Rights**

17           CIEA asserts that the rights Jackson acquired under the newly amended license agreement  
18 are illusory because Jackson will not actually practice its newly licensed right to make, use, sell,  
19 import, or offer for sale CIEA owned or developed mice with the IL2rg gene. As discussed above,  
20 the amendment grants Jackson both the right to make, use, sell, import, or offer for sale CIEA  
21 owned or developed mice with the IL2rg gene and the right to sublicense CIEA to do the same.  
22 Jackson claims that it may decide to distribute CIEA's NOG mice at some point in the future.  
23 Regardless of whether Jackson actually exercises its newly acquired rights, there is no question that  
24 the amendment has broadened the scope of what Jackson may do with respect to the '173 Patent.  
25 Though CIEA may be correct that Jackson's purpose in acquiring these rights is to pursue litigation,  
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1 this motive does not change the substantive effect of the amendment.<sup>2</sup> Therefore, the court finds that  
2 the rights granted are substantive and cannot be dismissed as merely illusory.

3 **2. Exclusionary Rights**

4 Because it is clear that Jackson's license under the '173 Patent now covers CIEA's NOG  
5 mouse, CIEA rehashes its earlier argument that exclusionary rights are always required to find injury  
6 in fact in a patent infringement suit, even after passage of the Bayh-Dole Act. According to CIEA,  
7 the court's previous ruling (which held otherwise) is erroneous because allowing non-exclusive  
8 licensees of government-owned patents to bring suit: (1) encourages trafficking in patent claims, (2)  
9 exposes infringers to a multiplicity of suits, (3) is contrary to the language in 35 U.S.C. § 207, which  
10 allows the grant of enforcement rights "pursuant to the provisions of chapter 29 of this title," and (4)  
11 is contrary to the legislative history of 35 U.S.C. § 207.

12 **a. Trafficking in Patent Claims**

13 The court acknowledges the well-established rule that "[a] patentee may not give a right to  
14 sue to a party who has no proprietary interest in the patent." *Ortho Pharm. Corp. v. Genetics Inst.*,  
15 52 F.3d 1026, 1034 (Fed. Cir. 1995) (citing *Crown Die & Tool Co. v. Nye Tool & Machine Works*,  
16 261 U.S. 24, 44 (1923)). This limitation discourages trafficking in patent claims. As explained in  
17 its earlier order, it is for this very reason that the court held that even under 35 U.S.C. § 207, a  
18 licensee does not have standing to sue unless the alleged infringing conduct is within the field of use  
19 for which the licensee has been granted patent rights. January 12, 2010 Order at 5. This  
20 requirement serves as a check on the potential for trafficking in patent claims by forcing the patent  
21 owner to hand over a portion of its proprietary rights in the patent in order to effect a transfer of  
22 enforcement rights.

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26 <sup>2</sup> *Propat Int'l Corp. v. RPost, Inc.*, 472 F.3d 1187 (Fed. Cir. 2007), does not suggest otherwise. The  
27 Federal Circuit did not base its holding in *Propat* on the motivation of the parties to the license  
28 agreement or whether the licensee actually exercised all of the rights granted to it. Instead, the  
Federal Circuit looked at the substantive rights conveyed by the terms of the licensing agreement,  
and based on those rights, it concluded that the licensee of a privately-owned patent lacked standing  
to bring suit. *Id.* at 1194.

**b. Exposing Infringers to Multiple Suits**

CIEA contends that non-exclusive licensees cannot have standing to bring suit because this would expose infringers to a multiplicity of suits. The Federal Circuit considered a similar argument in *Nutrition 21*. In *Nutrition 21*, the defendant argued that it would be prejudicial to remove the prudential standing requirement that a licensee must join the patent owner to any infringement suit because the patent owner would not be bound by the outcome of a lawsuit by its licensee, either by res judicata or collateral estoppel. 930 F.2d at 867. Nonetheless, the Federal Circuit held that after the passage of the Bayh-Dole Act, a licensee of a government-owned patent is no longer required to join the patent owner to bring suit when the government has granted the licensee the right of enforcement. *Id.* Likewise, the court finds that, even if there is the possibility that an infringer could face a multiplicity of suits,<sup>3</sup> 35 U.S.C. § 207 permits non-exclusive licensees of government-owned patents to bring suit when certain conditions are met.

**c. Statutory Language**

According to CIEA, the Bayh-Dole Act limits the grant of enforcement rights to exclusive licensees because the statutory language states that federal agencies may grant "the right of enforcement *pursuant to the provisions of chapter 29 of this title*." 35 U.S.C. § 207(a)(2)(emphasis added). CIEA relies upon 35 U.S.C. § 281, a provision under chapter 29 which states: "A patentee shall have remedy by civil action for infringement of his patent." However, 35 U.S.C. § 281 does not limit Article III standing to patentees and assignees. *Intellectual Property Development, Inc.*, 248 F.3d at 1346. In order to determine whether a party has constitutional standing, one must apply the test articulated in *Lujan*. *See id.* at 1346-47 (applying the *Lujan* test to determine standing).

Of the three standing requirements set forth in *Lujan*, the only one that is disputed in this case is the requirement of an injury in fact. Injury in fact refers to "an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560 (quotations and citations omitted). CIEA does not claim that

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<sup>3</sup> The court notes that it is not clear that an infringer would actually be prejudiced by a multiplicity of suits. At this time, the question of what preclusive effect a lawsuit by one licensee would have on the patent owner or other licensees is not properly before it.

1 the injury caused by the alleged infringement is not sufficiently concrete, particularized, actual, or  
2 imminent. Rather, it asserts that Jackson has no legally protected interest.

3 With respect to privately-owned patents, CIEA is correct: non-exclusive licensees have no  
4 legally protected interest that is invaded by infringement. *Morrow*, 499 F.3d at 1340-41. Courts  
5 have recognized that non-exclusive licensees can suffer harm from infringement, but they have  
6 traditionally precluded non-exclusive licensees from bringing suit for policy reasons. *See Ortho*, 52  
7 F.3d at 1031 ("there are strong policy reasons why patent law does not confer standing on a  
8 nonexclusive licensee to sue a third party for infringement even though the licensee has suffered due  
9 to the infringement") (quoting *A.L. Smith Iron Co. v. Dickson*, 141 F.2d 3, 6 (2nd Cir. 1944)).

10 The reason why [a nonexclusive licensee] is not permitted to sue is not because he  
11 has nothing to protect. But against that interest is the interest of the infringer to be  
12 immune from a second suit by the owner of the patent; and also the interest of the  
13 patent owner to be free to choose his forum . . . . Indeed, the owner may have granted  
a number of licenses, and it would be exceedingly oppressive to subject him to the  
will of all his licensees. These two interests in combination have been held to  
overweigh any interest of the licensee.

14 *A.L. Smith Iron Co.*, 141 F.2d at 6. Due to these policy considerations, non-exclusive licensees of  
15 privately-owned patents are deemed to have suffered no legal injury and thus barred from bringing  
16 suit.

17 However, the Bayh-Dole Act changed the standing requirements for government-owned  
18 patents. *See Nutrition 21*, 930 F.2d at 865 (disregarding earlier case on patent standing because it  
19 "did not involve a government-owned patent, and the relevant law has been changed by Congress").  
20 The Federal Circuit found that "35 U.S.C. § 207(a)(2) authorizes the grant of enforcement rights to  
21 'nonexclusive, exclusive or partially exclusive licensees. . . ." *Id.* at 865 n.7.<sup>4</sup> Thus, as explained in  
22 this court's earlier order, "[w]hile there are policy reasons for limiting standing to exclusive licensees  
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24 <sup>4</sup> In this footnote, the Federal Circuit had noted that the applicable Department of Commerce  
25 regulations at the time appeared to limit the grant of enforcement rights to "domestic exclusive and  
26 partially exclusive licensees." *Nutrition 21*, 930 F.2d at 865 n.7 (citing 37 C.F.R. §  
27 404.7(a)(2)(iv)(1990)). The court notes that after the *Nutrition 21* decision, these regulations were  
28 amended to remove the provision which had appeared to earlier limit the grant of enforcement rights  
to exclusive and partially exclusive licensees. 71 Fed. Reg. 45, 11513 (Mar. 8, 2006). In addition,  
the regulations now include a provision explicitly stating that "[a]ny patent license may grant the  
licensee the right of enforcement of the licensed patent without joining the Federal agency as a party  
as determined appropriate in the public interest." 37 C.F.R. § 404.5(b)(2).

1 in most patent infringement cases, Congress saw fit to expand the pool of parties with standing to  
2 sue for infringement of government-owned patents with its enactment of 35 U.S.C. § 207."<sup>5</sup> January  
3 12, 2010 Order at 4. Congress has the power to change standing requirements through legislation  
4 because "[t]he actual or threatened injury required by Article III may exist solely by virtue of  
5 statutes creating legal rights, the invasion of which creates standing." *Warth v. Seldin*, 422 U.S. 490,  
6 500 (1975) (quotations omitted). By empowering federal agencies to grant enforcement rights to  
7 non-exclusive licensees, 35 U.S.C. § 207 created a legally protected interest, such that non-exclusive  
8 licensees may bring suit when certain conditions are met.

9 **d. Legislative History**

10 Finally, CIEA argues that the legislative history of the Bayh-Dole Act shows that Congress  
11 intended to limit the grant of enforcement rights to exclusive licensees. It points to the fact that the  
12 original text of the Bayh-Dole Act explicitly provided for "enforcement of an exclusive license  
13 under the Chapter by an exclusive licensee" and did not provide for enforcement rights by non-  
14 exclusive licensees. However, the final text of the Bayh-Dole Act does not contain any such  
15 limitations. One could interpret this legislative history as showing Congressional intent *not* to limit  
16 the grant of enforcement rights to exclusive licensees, since Congress chose to abandon the  
17 provision containing an explicit limitation. At best, this legislative history is inconclusive and does  
18 not provide support for CIEA's position.

19 **D. Certification for Interlocutory Appeal**

20 CIEA asks the court to certify the issue of Jackson's standing for interlocutory appeal. When  
21 a court finds that its ruling "involves a controlling question of law as to which there is substantial  
22 ground for difference of opinion and that an immediate appeal from the order may materially  
23 advance the ultimate termination of the litigation," the court may certify the issue for interlocutory  
24 appeal. 28 U.S.C. § 1292(b). Such certification for interlocutory appeal is only meant for  
25 "exceptional situations," *In re Cement Antitrust Litigation*, 673 F.2d 1020, 1026 (9th Cir. 1982), and  
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27 <sup>5</sup> Perhaps in recognition of the need to balance varying policy considerations, the Bayh-Dole Act  
28 limits the granting of enforcement rights to situations where it is "determined appropriate in the  
public interest." 35 U.S.C. § 207(a)(2).




"was not intended merely to provide review of difficult rulings in hard cases," *U.S. Rubber Co. v. Wright*, 359 F.2d 784, 785 (9th Cir. 1966).

CIEA has not pointed to any cases dealing with government-owned patents where a court has come to a conclusion contrary to this court's ruling. Moreover, the mere fact that the Federal Circuit has not yet ruled on this issue directly is insufficient to establish a substantial ground for difference of opinion. *See, e.g., In re Flor*, 79 F.3d 281, 284 (2nd Cir. 1996) ("the mere presence of a disputed issue that is a question of first impression, standing alone, is insufficient to demonstrate a substantial ground for difference of opinion"); *White v. Nix*, 43 F.3d 374, 378 (8th Cir. 1994) ("substantial ground for difference of opinion does not exist merely because there is a dearth of cases"). The court finds that CIEA has failed to establish a substantial ground for difference of opinion and thus declines to certify the issue of Jackson's standing for interlocutory appeal.

### III. ORDER

For the foregoing reasons, the court denies CIEA's motion to dismiss Jackson's patent infringement counterclaim and denies CIEA's motion for certification for interlocutory appeal.

DATED: 3/26/10

  
RONALD M. WHYTE  
United States District Judge

1 Notice of this document has been electronically sent to:

2 **Counsel for Plaintiff:**

3 Joseph Diamante JDiamante@stroock.com  
Kenneth E. Keller kkeller@kksrr.com  
4 Michael David Lisi mlisi@kksrr.com  
Ronald Marc Daignault rdaignault@stroock.com

5 **Counsel for Defendant:**

6 Chelsea A Loughran cloughran@wolfgreenfield.com  
7 Howard Alan Slavitt EfilingHAS@cpdb.com  
Michael A. Albert malbert@wolfgreenfield.com  
8 Michael Rader mrader@wolfgreenfield.com  
Allison Lee Ehlert ale@cpdb.com

9  
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14 **Chambers of Judge Whyte**